DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 8 2009

Re: INTELENCE
Docket No.: FDA-2008-E-0307

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 7,037,917, filed by Janssen Pharmaceutica, N.V., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for INTELENCE (etravirine), the human drug product claimed by the patent.

The total length of the regulatory review period for INTELENCE (etravirine) is 2,235 days. Of this time, 2,050 days occurred during the testing phase and 185 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: December 7, 2001.

   The applicant claims December 27, 2001, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the applicant was notified by telephone on December 7, 2001, that they were allowed to proceed with clinical trials. The IND effective date was December 7, 2001.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: July 18, 2007.

   FDA has verified the applicant's claim that the new drug application (NDA) for INTELENCE (etravirine) (NDA 22-187) was initially submitted on July 18, 2007.

3. The date the application was approved: January 18, 2008.

   FDA has verified the applicant's claim that NDA 22-187 was approved on January 18, 2008.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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